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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,975	03/03/2004	John A. Kao	11380.1	4853
7590	11/14/2007			
Attn: NEIL K. NYDEGGER NYDEGGER & ASSOCIATES 348 Olive Street San Diego, CA 92103			EXAMINER NGUYEN, VI X	
			ART UNIT 3734	PAPER NUMBER
		MAIL DATE 11/14/2007	DELIVERY MODE PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/791,975	KAO, JOHN A.
	Examiner Victor X. Nguyen	Art Unit 3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED' (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 October 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
  - 4a) Of the above claim(s) 12-20 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,5-9 and 11 is/are rejected.
- 7) Claim(s) 4 and 10 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/27/04</u> .   | 6) <input type="checkbox"/> Other: _____.                         |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I, claims 1-11 in 10/17/2007 is acknowledged.

Claims 12-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected species, there being no allowable generic or linking claim.

Election was made **without traverse** in the reply filed on 10/17/2007.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. None of the drawings of Applicant illustrates a reference number for *an ultra-sonic transducer*.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

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be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In **claim 1**, the disclosure does not describe “a means for activating said transceiver to radiate a signal therefrom toward a vessel wall in the vasculature and to receive said signal as a return signal after reflection thereof from the vessel wall”. This limitation was presented in the specification filed 3/3/2004 and yet only on page. 8 of applicant’s specification, lines19-22 does mention “each reflection generates an acoustic return signal that is received by the transmitting transceiver and converted to an electrical return signal”. However, it does not disclose that this means for activating said transceiver to radiate a signal therefrom toward a vessel wall in the vasculature and to receive said signal as a return signal after reflection thereof from the vessel wall as is now claimed. Clarification is requested.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3,5-9 and 11 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Wilson et al. (6,955,688) in view of Soykan et al (6,236,889).

Wilson et al disclose in figures 9a,b, a stent at a bifurcation in the vasculature as recited in claims 1 and 8, including: a catheter 31, an expandable means at 35 mounted on the catheter and is engageable with a stent at 10. However, Wilson is silent regarding a system having a transceiver, a means for activating the transceiver and an extracorporeal means or acoustic transducer crystal to evaluate the position of the stent at the bifurcation. Soykan et al teach a transceiver (see col. 2, lines 39-40), a means for activating the transceiver (see col. 10, lines 56-62) and an extracorporeal means (for example, a controller 25) or acoustic transducer crystal 22 to evaluate the position of the stent at the bifurcation. It would have been obvious to one having ordinary skill in the art at the same time the invention was made to modify Wilson et al by making a system having a transceiver, a means for activating the transceiver and an extracorporeal means or acoustic transducer crystal as taught by Soykan in order to enhance the effectiveness of determining the location of a lesion, because one of ordinary skill in the art would have been capable of applying this known method of determining of the location of a lesion in the prior art and the results would have been predictable to one of ordinary skill in the art. As to claims 2,5-7,9 and 11, Wilson discloses a guidewire at 36a, where the bifurcation is an aortic-ostium (see fig. 9a), and where the expandable means is a balloon at 35 and is able to move

between a deflated configuration and an inflated configuration, and where the stent is released from the balloon (see fig. 13e). As to claim 3, Soykan discloses a single acoustic transceiver may be employed (see col. 2, lines 39-40). At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify Wilson and Soykan device with an ultrasonic transducer because Applicant has not disclosed that an ultrasonic transducer provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Soykan device and applicant's invention, to perform equally well with either the device taught by Soykan because both device would perform the same function of being an implantable medical device and generated a carrier signal. Therefore, it would have been obvious to modify Soykan to obtain the invention as specified in the above claim because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Soykan.

***Allowable Subject Matter***

5. Claims 4,10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C .112 set forth in this Office action.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victor X Nguyen  
Examiner  
Art Unit 3734



VN ✓  
11/5/2007



MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER